

**REMARKS**

Applicant's attorney gratefully acknowledges the July 26, 2005 telephone interview with the Examiner, Dwayne K. Handy.

The following remarks summarize the discussion during the July 26, 2005 telephone interview with Mr. Handy.

The objection to the specification under 35 USC §132(a) based on new matter introduced by the recitation of magnetic detection means in claim 27 and the rejection of claim 27, under 35 USC §112 is failing to comply with the written description requirement should be withdrawn. This is because magnetic detection means were recited in original claim 9, and the original claims form part of the specification.

Accordingly, it is respectfully submitted that magnetic detection means do not constitute new matter in claim 27. The language in original claim 9 can be introduced into a suitable location in the disclosure, for example at page 2, first full paragraph, as shown in the "AMENDMENTS TO THE SPECIFICATION" on page 2 of this Proposed Amendment. Alternatively, Applicant can also amend the disclosure in a similar manner at page 5, line 9, by adding a new sentence to recite that magnetic detection means can also be used in addition to the optical detection system.

With regard to the joint inventorship issue raised on page 3 of the Office Action, it is noted that this application has a single inventor, and

the subject matter of all claims was commonly owned at the time the invention covered herein was made.

Before discussing the prior art, it is believed worthwhile at this point to review the novel aspects of the claimed invention.

The specification discloses that known systems typically deliver a fixed volume of a diluted sample solution at a fixed rate for **quantitative** (i.e., **counting**) and **qualitative** (i.e., **characterizing**) the cells (page 2 at lines 3-4).

The claimed invention relates to *quantitative* means for *counting* the cells, rather than qualitative means for characterizing the cells.

The Abstract of the invention states as follows:

*"A variable rate particle counter for adjusting the volumetric delivery rate of fluid to a flow cell based on an initial particle count rate in order to effectively 'tune' the final dilution of sample sheath flow to the particle concentration of the sample. A sheath fluid syringe pump and a test sample syringe pump are driven by motors which are adjusted by a data analyzer. The data analyzer compares particle count rate measured by a detection assembly to a predetermined reference value and determines if the count rate is too high or too low. Accordingly, one of several pump profiles is initiated to adjust the flow rate of the sheath fluid or test sample or both. Advantageously, the low cell count precision is improved and the upper limit cell count is expanded."* (emphasis added)

It would be readily apparent to one of ordinary skill in the art that the claimed invention is directed to a quantitative method for improving the precision in counting the number of particles or cells suspended in a given volume of a test sample wherein the number of particles or cells ranges from

low particle/cell counts to high particle/cell counts, and not a qualitative characterizing procedure as disclosed in U.S. Patent No. 5,106,187 to Bezanson.

Bezanson relates to the detection and analysis of particles in a sample fluid to identify and characterize various particles, not to a quantitative method for improving the precision in counting the number of particles or cells suspended in a given volume of test sample, as claimed by Applicant.

Bezanson states at column 1, lines 12-17 as follows:

*"The apparatus of this invention is particularly useful in the monitoring of industrial processes and the identification of various particles without the intervention of human operators. Typical applications are in oceanography or industrial applications such as milk analysis."* (emphasis added)

Bezanson further states at column 1, lines 40-46 as follows:

*"The present application relates to an improved apparatus which enables the signal from each of the conductivity, scattering and fluorescent detectors to be stored as separate waveforms so that the various waveforms relating to a single particle can be used as a composite source of information to establish the identity and characteristics of a particle."* (emphasis added)

Bezanson's disclosure thus deals with the qualitative analysis of the identity and characteristics of particles and not the quantitative aspect of improving the precision of counting particles, as claimed by Applicant.

Claim 23 has been amended in a sincere effort to clarify Applicant's invention. No new matter has been added.

The Examiner's rejection of claims 23, 24, 26, 28, and 29 under 35 USC §103 as unpatentable over U.S. Patent No. 5,106,187 to Bezanson in view of U.S. Patent No. 5,895,764 to Sklar et al should be reconsidered and withdrawn.

The Examiner admits that Bezanson teaches a method and apparatus for particle identification. Therefore, the Examiner's attempt to extrapolate Bezanson's teachings to a method for improving the precision of counting particles, as claimed by Applicant, is unjustified.

The Examiner's reliance on Bezanson at column 2, lines 11-23 as delivering a sample in a sheath fluid stream does not disclose nor suggest a means for improving the precision in counting the number of particles or cells in a given volume of test sample.

The Examiner's reliance on Bezanson at column 2, lines 38-42 as detecting the characteristic of the sample has no relation whatsoever to Applicant's claimed invention for improving the precision in counting the number of particles or cells suspended in a given volume of test sample.

The Examiner's reliance on Bezanson at Figure 3 and column 3, lines 37-65, discloses the use of a computer to analyze signals and compare signals to preset limits, to identify particles and to measure the surface

characteristics (column 4, lines 9-12 and 18-20), not to a method for improving the precision in counting the number of particles or cells in a given volume of test sample, as claimed by Applicant.

The Examiner's reliance on Bezanson at column 3, lines 24-28 teaches controlling pumping rates to control particle speed in a sensing zone to produce optimum waveform resolution for the identification of particles, and not to a method for improving the precision in counting particles, as claimed by Applicant.

Accordingly, it is respectfully submitted that Applicant's claimed invention is patentably distinct over Bezanson.

The Examiner's additional reliance upon U.S. Patent No. 5,895,764 to Sklar et al does not resolve the deficiencies of Bezanson but rather compounds them. Thus, Sklar's invention relates to flow cytometers as valuable tools for mechanistic studies of molecular interactions, such as cell function (column 1, lines 5-7), and has no relation to a method for improving the precision of counting particles, as claimed by Applicant.

The objective of Sklar's invention is to control sheath flow in a flow cytometer to enhance and clarify particle analysis, not to improve the precision of counting the number of particles as claimed by Applicant (column 2, lines 37-39).

The Examiner's reliance on Sklar at column 3, lines 25-27 and 60-67, is in the context of a method for controlled sheath flow cytometry to yield stable laminar flow, and does not disclose Applicant's claimed invention in an obvious manner.

The Examiner concludes the rejection by stating:

*"Both Sklar et al and Bezanson use flow cells to analyze the particles which are present in the sample."*

In essence, the Examiner confirms that the combination of Sklar et al and Bezanson relate to the qualitative analysis of particles, not to a method for improving the precision of counting the number of particles or cells suspended in a given volume of a test sample as claimed by Applicant. Accordingly, it is respectfully requested that this ground of rejection be reconsidered and withdrawn.

The rejection of claim 25 under 35 USC §103 as unpatentable over Bezanson and Sklar et al further in view of U.S. Patent No. 5,488,469 to Yamamoto et al should also be reconsidered and withdrawn. The deficiencies of Bezanson and Sklar et al have already been discussed and are equally applicable herein.

Yamamoto discloses a cell analyzing apparatus in which detection precision is improved so that the condition of a disease may be understood more accurately, and provides a cell analyzing apparatus capable

of discriminating an abnormal specimen, and wherein the reliability and interchangeability of analytic information can be assured even if the cell count of a cell of interest in a measured sample does not attain a predetermined cell count (column 2, line 61 to column 3, line 5).

It is respectfully submitted that the added reliance of Yamamoto et al in combination with Bezanson and Sklar does not obviously suggest Applicant's claimed method.

Accordingly, it is respectfully requested that this ground of rejection be reconsidered and withdrawn.

It is respectfully submitted that this application is now in condition for allowance and such favorable action is respectfully requested.

Respectfully submitted,

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